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Section 5: 510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for the **NOCC™** Hydrophilic Wound Dressing 510(k) premarket notification.

The safety and effectiveness of the **NOCC™** Hydrophilic Wound Dressing is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate devices.

Sponsor: Kytogenics Pharmaceuticals, Inc.
Adams Building, 1st Floor
466 Southern Boulevard
Chatham, NJ 07928
Ph. 973-410-0200
Fax. 973-410-0220

Contact: Marina Zazanis, President & CEO

Date of Submission: December 28, 2007

Proprietary Name: **NOCC™** Hydrophilic Wound Dressing

Common Name: dressing, wound and burn, hydrogel w/drug and/or biologic, hydrophilic wound dressing

Regulatory Class: Unclassified

Product Codes: MGQ, dressing, wound and burn, hydrogel w/drug and/or biologic

Predicate Devices: Bionect Clear Hydrogel, Fidia Pharmaceutical (K984264)

Device Description

NOCC™ (N,O-Carboxymethylchitosan) Hydrophilic Wound Dressing is a hydrogel that provides a moist wound environment to support wound healing. The gel is clear which aids in visualization of the wound.

Intended Use

NOCC™ Hydrophilic Wound Dressing is indicated in the dressing and management of minor burns, superficial cuts, lacerations, and abrasions; minor irritations of the skin. A health care professional may be consulted prior to the first use of the product

to determine whether these conditions exist. Kytogenics' Hydrophilic Wound Dressing may also be used under the care of a health care professional for wounds such as partial thickness dermal ulcers (pressure sores, venous stasis ulcers, diabetic ulcers) surgical wounds (post operative incisions and donor sites, and second degree burns.

Comparison to predicate device

Company	**Kytogenics Pharmaceuticals, Inc.**	**Fidia Pharmaceutical**
Proprietary Name	**NOCC™** Hydrophylic Wound Dressing	Bionect Clear Hydrogel
510(k) Number	not assigned	K984264
Intended use	Same	Same
Material Characteristics	chitosan based hydrogel	Hyaluronic acid sodium salt hydrogel
Forms	clear hydrogel	clear hydrogel
How supplied	Sterile	Sterile
Sterilization Method	Moist heat	Gamma Irradiation
Packaging	polyethylene bottles	tube

Summary of Technological Characteristics

NOCC is similar in structure to Hyaluronic Acid (HA) and shares many of the same properties. Both materials are highly hydrated, lubricious, viscoelastic, biocompatible and bioresorbable.

Summary of Nonclinical Tests

Numerous studies, as well as over 10 years of evaluation, have demonstrated that NOCC is bioresorbable and biocompatible. The technology has been shown to have excellent bioadhesion to both soft tissue (mucosal) and hard tissue (bone).

Technological Characteristics and Substantial Equivalence

The claim of substantial equivalence of **NOCC™** Hydrophilic Wound Dressing to the predicate device is based on the comparison of the intended use, product technical characteristics, and performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 14 2008

Kytogenics Pharmaceuticals, Inc.
% Ms. Marina Zazanis
President & CEO
466 Southern Boulevard
Adams Building, 1st Floor
Chatham, New Jersey 07928

Re: K080010
Trade/Device Name: NOCC™ Hydrophilic Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 29, 2008
Received: March 03, 2008

Dear Ms. Zazanis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Section 4: Indications for Use Statement

510(k) Number: To be assigned

Device Name: **NOCC™** Hydrophilic Wound Dressing

Indications for Use: Hydrophilic Wound Dressing is indicated in the dressing and management of minor burns, superficial cuts, lacerations, and abrasions; minor irritations of the skin. A health care professional may be consulted prior to the first use of the product to determine whether these conditions exist. Kytogenics' Hydrophilic Wound Dressing may also be used under the care of a health care professional for wounds such as partial thickness dermal ulcers (pressure sores, venous stasis ulcers, diabetic ulcers), surgical wounds (post operative incisions and donor sites, and second degree burns.

Prescription Use ___X____ AND/OR Over-The-Counter Use ____X___

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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